NOV 1 6 2001

510(k) Summary

K013206

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 521 - 3544

Contact Person: Kay A. Taylor

Date Prepared: September 24, 2001

Device Name

Proprietary name: Tina-quant Apolipoprotein ver.2

Common name: Apolipoprotein B

Classification name: Low-density lipoprotein immunological test system

Device Description

A device for the measurement of human apolipoprotein B in serum or plasma. Anti-apolipoprotein B antibodies react with the antigen in the sample to form antigen/antibody complexes which, following agglutination, are measured turbidimetrically.

Intended use

Immunoturbidmetric assay for the in vitro quantitative determination of apolipoprotein B in human serum and plasma on automated clinical chemistry analyzers.

Indications for Use

A lipoprotein test system is a device intended to measure lipoprotein in serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders and atherosclerosis.

Substantial Equivalence

The Tina-quant Apolipoprotein B ver.2 is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Dade Behring N Antisera to Human Apolipoprotein A-1 and Apolipoprotein B assay (K860894).

Substantial equivalence - similarities

The following table compares the Tina-quant Apolipoprotein B ver.2 Assay with the predicate device.

Feature	Tina-quant Apolipoprotein B ver.2	Apolipoprotein B (predicate)
Intended Use	Immunoturbidmetric assay for the in vitro quantitative determination of apolipoprotein B in human serum and plasma on automated clinical chemistry analyzers.	In vitro diagnostic reagent for the quantitative determination of apolipoprotein B in human serum with the Behring nephelometers.
Indication for Use	For the quantitative determination of apolipoprotein B in serum and plasma. A lipoprotein test system is a device intended to measure lipoprotein in serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders and atherosclerosis.	For the quantitative determination of apolipoprotein B in serum and plasma. A lipoprotein test system is a device intended to measure lipoprotein in serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders and atherosclerosis.
Assay Protocol	Immunoturbidometric	Immunoturbidometric
Traceability / Standardization	Standardized with regard to the IFCC reference preparation SP3-07.	Not provided in insert
Calibration Interval	• After each lot • as required by QC procedures	• After each lot • as required by QC procedures

Substantial equivalence – differences

The following table compares the Tina-quant Apolipoprotein B ver.2 Assay with the predicate device.

Feature	Tina-quant Apolipoprotein B ver.2	Apolipoprotein B (predicate)
Sample Type	Serum and plasma (heparin, EDTA)	Serum
Reagent Stability	• Store at 2-8°C, unopened. • 42 days opened and refrigerated on analyzer.	• Store at 2-8°C, unopened. • Use within 4 weeks, if directly after use if vials are stopped, capped and stored at 2-8°C. • Do not use remaining antiserum if left open on nephelometer for longer than 5 days at 8 hours daily or comparable period of time. • Do not freeze.
Calibrator	C.f.a.s. Lipids	N Apoliporprotein Standard Serum (human)
Controls	Precinorm L, Precipath L	Apolipoprotein Control Serum CHD (human)
Expected Values	Females: 60 - 117 mg/dL Males: 66 – 133 mg/dL	Females: 0.66 – 1.25 g/L Males: 0.65 – 1.40 g/L
Instrument	Roche/Hitachi Clinical Chemistry Analyzers	Dade Behring Nephelometers
Measuring Range	20 - 400 mg/dL	Not provided in insert

Substantial equivalence – performance characteristics

The performance characteristics of the Tina-quant Apolipoprotein B ver.2 Assay and the predicate device are compared in the table below.

Feature	Tina-quant Apolipoprotein B ver.2	Apolipoprotein B (predicate)
Precision	**Within run CV** 1.5% @ 29 mg/dL (serum) 0.5% @ 112 mg/dL (serum) 0.8% @ 69 mg/dL (control) 0.5% @ 152 mg/dL (control) **Between Day CV** 2.5% @ 26 mg/dL (serum) 1.1% @ 127 mg/dL (serum) 1.0% @ 80 mg/dL (control) 1.9% @ 155 mg/dL (control)	**Inter-assay Precision** 1.9% CV @ 1.04 g/L **Intra-assay Precision** 2.4% CV @ 1.08 g/L
Method Comparison	Bablok/Passing: Tina-quant Apolipoprotein B ver.2 (Y) / Nephelometric method (X). y = 1.127 – 2.849 mg/dL r = 0.884	Dade Behring N Antisera Apo B (Y) / radioimmunodiffusion commerical method (X): y(BN)= 0.94(RID) – 0.004 g/L r= 0.99
Hook Effect	No effect up to 600 mg/dL	NA
Analytical sensitivity (LDL)	1.5 mg/dL	Established by the lower limit of the reference curve and depends therefore upon the concentration of the proteins in the N Apolipoprotein Standard Serum.

Substantial equivalence – performance characteristics, cont.

The performance characteristics of the Tina-quant Apolipoprotein B ver.2 Assay and the predicate device are compared in the table below.

Feature	Tina-quant Apolipoprotein B ver.2	Apolipoprotein B
Limitations	• Icterus: No significant interference up to an I index of 60 mg/dL (conjugated and unconjugated) • Hemolysis: No significant interference up to an H index of 1000. • Lipemia: No significant interference up to an L index of 1000. • Anti-human apolipoprotein B antibodies from sheep show no cross-reactivity with apolipoprotein A-I or A-II.	• Turbidity and particles in the sample can interfere with the test. Therefore particulates resulting from incompleted coagulation or denaturation of proteins should be removed prior to assay by centrifugation. • In isolated cases excessive concentrations of triglycerides or hyperlipemic samples may disturb the Apo B assay. In such cases the effect of the disturbance can be reduced by retesting the sample in a higher dilution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 1 6 2001

Ms. Kay A. Taylor
Regulatory Submissions, Centralized Diagnostics
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k013206
Trade/Device Name: Tina-quant Apolipoprotein B ver.2
Regulation Number: 21 CFR 866.5600
Regulation Name: Low-density lipoprotein immunological test system
Regulatory Class: Class II
Product Code: DFC
Dated: September 24, 2001
Received: September 25, 2001

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number (if known): N/A K013206

Device Name: Tina-quant Apolipoprotein B ver.2

Indications For Use:

Immunoturbidmetric assay for the in vitro quantitative determination of apolipoprotein B in human serum and plasma on automated clinical chemistry analyzers.

A lipoprotein test system is a device intended to measure lipoprotein in serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders and atherosclerosis.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013206